UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MEMORANDUM

DATE: August 14, 2019

SUBJECT: Review or product performance data to evaluate the repellency of aged applications of end use product, Detour Gel for Rats, containing 0.0357 % w/w Capsaicin as its active ingredient, against rats.

Decision Number:	553247
DP Number:	453545
Submission Number:	1037337
EPA Reg. No.:	84418-1
Active Ingredient Type:	Biochemical
PC Code:	070701
CAS Number:	404-86-4
Active Ingredient Tolerance/Exemption:	N/A
MRID Number(s):	508975-01

FROM: Clara Fuentes, Ph.D., Entomologist
Risk Assessment Branch
Biopesticides & Pollution Prevention Division (7511P)

CLARA FUENTES Digitally signed by CLARA FUENTES Date: 2019.08.14 12:40:23 -04'00'

THROUGH: Russell S. Jones, Ph.D., Senior Scientist,
Risk Assessment Branch
Biopesticides & Pollution Prevention Division (7511P)

Russell S. Jones, Ph.D. Digitally signed by Russell S. Jones, Ph.D. Date: 2019.08.14 11:29:05 -04'00'

TO: Menyon Adams, Regulatory Action Leader
Biochemical Pesticides Branch
Biopesticides & Pollution Prevention Division (7511P)

ACTION REQUESTED

Bio-Repellent Scientific Industries, Inc. is requesting review of study protocol in MRID 508975-01, for conducting product performance testing on aged applications of Detour Gel for Rats in support of adding residual repellency claim to the product label for up to 30 days against rats.

SUMMARY OF SUBMITTED STUDY

MRID 508975-01, *Efficacy of Detour Gel Aged for 30 Days at Repelling Rats*:

The objective of the proposed study is to assess the repellency of 30-day old applications of Detour Gel for Rats to preventing rats from reaching their food and water under choice and non-choice scenarios. **The product is intended for use as a repellent/barrier in areas where traps are placed surrounding the gel application (Refer to product label)**. Label directions instruct users to apply ½ inch bead of product in a zig zag pattern on **surface areas where rats frequent and damage (Refer to product label)**.

The test animal is the albino rat, Sprague-Dawley. They will be individually housed in polycarbonate boxes provided with bedding, food and water, and maintained under laboratory conditions at temperature of 22 ± 3°C; RH = 30-70 %, and 12:12 light cycle. A total of 60 rats, mixed sex adults between 6 to 10 weeks old, will be used for testing repellency in a choice and non-choice situation**. Groups of 30 rats will be randomly assigned to choice, non-choice tests and controls (Section B. Experimental Design, under c. Quantity and Sex; pg. 3 of 8 in study protocol)**, **following a randomization procedure described as "weight-stratified randomization procedure"(Section B. Experimental Design under 4. Conduct of test a. Randomization; pg. 5 of 8 in study protocol)**. Each test will be replicated **5 times with 3 rats per replication for a total of 15 rats per test, including controls (Section B. Experimental Design, under c. Quantity and Sex; pg. 3 of 8 in study protocol).** Only naïve healthy animals will used for testing. Animals will be acclimated to test chambers containing food and water for 6 hours the day before testing and fasted overnight prior to testing. The non-choice test chambers are made of 1 meter clear plastic (PVC) tube of approximately 10 cm diameter with both ends open into 20 L polycarbonate plastic buckets. For non-choice test, food and water will be provided in one of the buckets. The other bucket will be used for release of single rats. **Testing will be done in pairs with each group represented (Section B. Experimental Design under 5. No-Choice Test Design b. Test Arena Design; pg. 5 of 8 in study protocol).** Rats will be released and observed individually. The choice test chamber has a T shape design with same dimensions as the non-choice one. Food and water will be provided in both buckets placed at both ends of the tee tube. Rats will be released and observed individually. **The test will be done in pairs with each group represented (Section B. Experimental Design under 5. No-Choice Test Design b. Test Arena Design; pg. 5 of 8 in study protocol).** For the non-choice, the product will be applied with a caulk gun in an approximately 1.27 cm (0.5 inches) bead in a zig zag pattern according to label instructions at a rate of 0.5 oz. per 1.5 ft. about 5 cm wide and 10 cm long on the bottom half of the inner surface of the tube at the beginning of the release bucket. The caulk tubes will be weighed pre- and post-application for accuracy of the amount applied to each tube. For the choice test, the product will be applied in a like manner to only one side of the tee tube. Placement of treatment applications will alternate between left and right of the tee tube across replications. Treated tubes will be stored for 30 days prior to test initiation.

One group of test arenas won't be treated with the product and will be used as control (Section B. Experimental Design under 3. Test Substance Administration; pg. 4 of 8 in study protocol).

Rats' behavior will be videotaped in the dark under red light for 2 hours. Food consumption during acclimation period and for each observation period will be recorded. Data will be analyzed by **unpaired t-test and other statistical analysis as appropriate for determination of statistical significance between treatment and control means (Section B. Experimental Design under 10. Statistical Analysis; pg. 6 of 8 in study protocol)**. Repellency will be estimated by the frequency of times rats were prevented by the test substance barrier from crossing the barrier and reach food and water.

COMMENTS, RECOMMENDATIONS and CONCLUSIVE REMARKS

The following recommendations should be followed to upgrade the study protocol in MRID 608975-01 to acceptable:

The label statements:

The statement, "*apply to surface areas where rats frequent and damage*" implies any type of substrate, porous and non-porous surfaces. If the product is only tested on plastic, the label should limit application of the product to non-porous surfaces. Otherwise, the product should be tested on different types of porous and non-porous surfaces to support the label statement "*apply to surface areas where rats frequent and damage.*" (Refer to label).

If the product was aged and tested indoors, the label should add language limiting efficacy claim and use of the product indoors. Otherwise, the product will have to be aged under outdoors conditions and then brought to the lab for testing.

Replications: **Section B. Experimental Design, under c. Quantity and Sex; pg. 3 of 8 in study protocol.**

The number of rats employed for testing needs to be increased to 200. That is 10 rats per replication. Five replications per test with 10 rats per replication results in a total of 50 rats per test. If there are 4 groups, consisting of choice and non-choice tests and 2 corresponding control groups for each test, the total number of animals needed is 200, randomly divided into 4 groups of 50 animals per test a control groups (choice test and control; non-choice test and control) with 10 rats per replication, and 5 replications per test and control group.

Randomization: **Section B. Experimental Design under 4. Conduct of test a. Randomization; pg. 5 of the study protocol.**

The randomization procedure in **Section B. Experimental Design under 4. Conduct of test a. Randomization; pg. 5 of the study protocol**, needs to be described in detail. Please, describe what is meant by "weight-stratified randomization"?

Repellency endpoint: **Section B. Experimental Design, under 8 Food Consumption on pg. 6 of 8 of the study protocol.**

It is stated under **Section B. Experimental Design, under 8 Food Consumption on pg. 6 of 8 of the study protocol** that food consumption will be recorded for the acclimation period and for each of the observation periods. The registrant should explain what is the purpose of measuring food consumption for the estimation of repellency and how this variable will be used for estimating repellency? In addition, the repellency endpoint for estimating/characterizing repellency should be identified in the study protocol.

Calculation of repellency:

Repellency should be expressed as percent reduction in barrier crossings relative to control by using Abbott's formula = C-T / C, where C is the mean number of times the control animals crossed to reached food and water and T is the mean number of times rats crossed the repellent barrier to reach food and water.

Statistical analysis: **Section B. Experimental Design under 10. Statistical Analysis; pg. 6 of 8 in study protocol.**

The plan for statistical analysis of data (**Section B. Experimental Design under 10. Statistical Analysis; pg. 6 of 8 in study protocol**) should be described in more detail.

Data from non-choice tests should be analyzed using an unpaired t-test with Welch's correction to compare frequency of crossings inhibition between treated and untreated surfaces at a significance level of $P< 0.05$.

Data from choice tests should be analyzed using a Chi square test with Fisher's exact test to compare crossing frequency between treated and untreated surface against control in a choice situation.

cc: Clara Fuentes, Menyon Adams, BPPD Chron. File, IHAD/ARS, FT, PY-S: 08/ 14/2019.